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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,137	06/15/2001	Mark L. Nelson	GAZ-065CP	8277

959 7590 08/08/2002

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/883,137

Applicant(s)

NELSON ET AL.

Examiner

Barbara P Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

First Office Action on the Merits

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites, "wherein said 4-amino substituent is dialkyl". Is said substituent "dialkyl" or "dialkylamino"? For the purpose of art rejection, it is assumed applicant intends the latter.

Claim 30 is dependent on claim 29 which recites "dimethyl" (it is assumed applicant intends "dimethylamino"). However, the instant claim recites compounds having other than a dimethylamino group.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

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scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

m 4. Claims 10-15 and 17-29 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3-9, 11-17, 19-23, 25 and 29 of copending Application No. 09/882,273. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

m 5. Claims 3, 5, 7, 9, 39 and ~~41~~ are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3, 6, 8, 10, 29 and 30 of copending Application No. 09/882,505. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- m 7. Claims 1, 2, 4, 6, 8, 10-30, 32-38 and 40-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 09/882,273. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to tetracycline compounds substituted in the 7-position with an N-substituted phenyl group. The claims of the present application differ from those of the copending Application by also reciting compounds having a halo substituted phenyl group in the 7-position of the tetracycline moiety.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

- m 8. Claims 1-9 and 31-64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of copending Application No. 09/882,505. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to tetracycline compounds substituted in the 7-position with an halo substituted phenyl group. The claims of the present application differ from those of the copending Application by also reciting compounds having an N-substituted phenyl group in the 7-position of the tetracycline moiety.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4, 8, 9, 24-30 and 58-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Koza.

Koza teaches 7-substituted tetracycline derivatives such 7-phenylsancycline, 7-(4-fluorophenyl)sancycline, 7-(4-nitrophenyl)sancycline, 7-(4-chlorophenyl)sancycline and 7-(4-dimethylphenyl)sancycline (see the entire article, especially page 816, Table 1, compound #s 1-6). The compounds taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-30, 32-45 and 47-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koza.

Koza teaches 7-substituted tetracycline derivatives such 7-phenylsancycline, 7-(4-fluorophenyl)sancycline, 7-(4-nitrophenyl)sancycline, 7-(4-chlorophenyl)sancycline and 7-(4-dimethylphenyl)sancycline (see the entire article, especially page 816, Table 1, compound #s 1-6).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. For example, claims 5-7, and 10-23 recite the claimed compounds having a 2- or 3-substituted phenyl group attached to the 7-position.

The compounds of claims 5-7 and 10-23 are positional isomers of the prior art compounds and, thus, are unpatentable unless they possess some unobvious or unexpected beneficial property not possessed by the prior art compounds. In re Norris, 179 F.2d 970, 84 USPQ 458 (CCPA 1970). The motivation to make positional isomers of the prior art compounds is based on the close structural similarity of the compounds and the expectation in the art that positional isomers would have similar properties.

Claims 37-45 and 47-57 differ from the reference by reciting treatment of a tetracycline responsive state such as bacterial infection. However, tetracycline and its derivatives are known broad-spectrum antibiotics useful against a vast number of bacterial infections (see Koza page 815, 1st paragraph). Thus, the use of any tetracycline derivative, including those taught by Koza and recited by the instant claims, in treating bacterial infections would be prima facie obvious. The motivation to use

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these compounds as recited by the instant invention would be based on the knowledge of the skilled artisan in the art and, thus, the expectation that any tetracycline derivative would be useful in treating tetracycline responsive disease states including bacterial infections.

Telephone Inquiry

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
August 7, 2002